

# Overview of Carbaryl Risk Assessment

## Introduction

This document summarizes EPA's human health and ecological risk findings and conclusions for the carbamate pesticide carbaryl, as presented fully in the revised documents, "*Human Health Risk Assessment: Carbaryl*" dated July 30, 2002 and "*Environmental Fate and Ecological Risk Assessment for the Reregistration of Carbaryl*" dated August 17, 2002. The purpose of this overview is to help the reader identify the key features and findings of these risk assessments and better understand EPA's conclusions. We developed this overview in response to comments and requests from the public which indicated that the risk assessments were difficult to understand, that they were too lengthy, and that it was not easy to compare the assessments for different chemicals due to differing formats.

Carbaryl is a carbamate insecticide, and it has been determined that N-methyl carbamates share a common mechanism of toxicity: the inhibition of cholinesterase. As required by the Food Quality Protection Act (FQPA), EPA will consider the cumulative risks from food, water and non-occupational exposure resulting from all relevant uses of the group of N-methyl carbamates. The risk estimates summarized in this document, however, are for carbaryl alone.

## Use Profile

Carbaryl (1-naphthyl methylcarbamate) is one of the most widely used broad-spectrum insecticides in agriculture, professional turf management, professional ornamental production, and in residential pet, lawn, and garden markets.

Based on sales information provided by the technical registrant Aventis in September 1998, it appears that approximately 34% of carbaryl is used by homeowners in residential settings, 59% is used in agriculture, and the remaining 7% is used in the nursery, landscape and golf course industries. According to Aventis, this information still reflects current trends.

- Technical Registrants. The technical registrants are Aventis, which provided the primary data for reregistration, and Burlington Scientific Corporation. Aventis is now owned by Bayer CropScience, and is still corresponding with EPA as Aventis, which is the legally recorded name on EPA pesticide registrations.
- Agricultural Uses. Carbaryl is used in agriculture to control pests on terrestrial food crops, including fruit and nut trees (e.g., apples, pears, almonds, walnuts, and citrus), many types of fruits and vegetables (e.g., cucumbers, tomatoes, lettuce, blackberries, and grapes), and grain crops (e.g., corn, rice, sorghum, and wheat).

### *Use Profile...*

Based on the Aventis sales data cited above, approximately 3.9 million pounds of active ingredient was sold to the agricultural market. Based on available usage information for the years 1987 through 1996, an annual estimate of carbaryl total domestic usage in agriculture averaged approximately 2.5 million pounds of active ingredient for over 1.5 million acres treated. Its largest agricultural markets (measured as the percentage of pounds active ingredient used annually) are pecans (12%), apples (9%), grapes (6%), oranges (5%), alfalfa (5%), and corn (4%). Most of this use was in Arkansas, California, Georgia, Illinois, Indiana, Michigan, Mississippi, Ohio, Oklahoma, and Texas. Crops with a high percentage of the total U.S. planted acres treated include Chinese cabbage (57%), asparagus (43%), cranberries (39%), Brussels sprouts (33%), apples (23%), and blueberries (22%).

- Residential Uses. Carbaryl is used by homeowners for lawncare, gardening (vegetables and ornamentals), and petcare. Apart from petcare, there are no labels for indoor uses. Carbaryl accounted for approximately 9% of the total residential insecticide market and was ranked fourth on the list behind the pyrethroids, chlorpyrifos, and diazinon (the latter two are now being removed from residential markets, so changes in market share are expected). Dusts (65%) and liquid concentrates (25%) account for most carbaryl sales in the residential market of 2 million pounds per year.
- Other uses. Carbaryl is used for ornamentals and turf, including production facilities, such as greenhouses and sod farms. It is used on golf courses and on residential sites treated by professional applicators (e.g., annuals, perennials, and shrubs). Carbaryl is also labeled for use as a mosquito adulticide, and EPA has assessed the risks from this use. Another carbaryl application examined in the risk assessment is a special local need use to control burrowing shrimp on oyster beds in Washington State.
- Formulations. Carbaryl formulations include baits, dusts, aerosol sprays, ready-to-use pump sprayers, pet collars, pet dips and shampoos, flowable concentrates, emulsifiable concentrates, granulars, soluble concentrates, water dispersible granules, and wettable powders.
- Methods of Application. Typical application methods in agriculture include groundboom, airblast, chemigation, and aerial. Carbaryl can also be applied using handheld equipment such as low and high pressure handwand sprayers, backpack sprayers, compressed air sprayers, and turfguns. Homeowners can apply carbaryl with equipment that includes trigger sprayers, hose end sprayers, ready-to-use dust packaging, belly grinders, push-type spreaders, and outdoor foggers.
- Application Rates. Carbaryl rates vary depending on the crop. For most of agriculture, maximum seasonal rates range from 1 to 16 pounds active ingredient per acre. Examples of high rate applications are tree nut crops and golf courses. Examples of low rate applications are certain field and row crops. Depending on the crop, the maximum number of carbaryl applications per season can range from 1 to 8. The maximum, single application rate for carbaryl is for California citrus only, specified on the label as up to 16 lb ai/acre.

## Human Health Risk Assessment

### Dietary Risk from Food

Carbaryl risks from food consumption are summarized in Table 1 below. Risks less than 100% of the Population Adjusted Dose (PAD), either acute (aPAD) or chronic (cPAD), are not of concern to the Agency. The aPAD is the dose at which a person could be exposed on any given day and no adverse health effects would be expected. The cPAD is the dose at which an individual could be exposed over the course of a lifetime and no adverse health effects would be expected. For the cancer dietary assessment, risks less than  $1 \times 10^{-6}$  are not of concern to the Agency.

**Table 1.** Summary of Dietary Exposure and Risk for Carbaryl (including Carbamate Market Basket Survey Data)

Population Subgroup	Acute (99.9 percentile)		Chronic		Cancer
	Exposure (mg/kg/day)*	% aPAD	Exposure (mg/kg/day)	% cPAD	Risk
U.S. Population	0.004580	46	0.000032	<1	$2.8 \times 10^{-8}$
Infants (<1 year old)	0.007272	73	0.000054	<1	NA
Children 1-6	0.007546	75	0.000057	<1	NA
*mg/kg/day= milligrams per kilogram per day.					

The acute and chronic (noncancer) dietary food risks are not of concern to the Agency; risks are less than 100% of both the aPAD and cPAD. Cancer dietary risk is also not of concern to the Agency as the risk to the general population of  $2.8 \times 10^{-8}$  is less than  $1 \times 10^{-6}$ . Below is a more detailed discussion of the dietary (food) risk estimates in Table 1.

### Acute Dietary (Food) Risk

Acute dietary (food) risk is calculated considering what is eaten in one day. In this instance, that includes the full range of consumption values as well as the range of residue values in food.

- For carbaryl, EPA conducted a Tier 3/4 dietary risk assessment, which is currently the most highly refined assessment possible. Dietary exposure was determined considering the level of carbaryl residues on food commodities and their potential consumption by multiple subpopulations, including infants and children. Acute dietary risk was then calculated by comparing dietary exposure to the aPAD.
- As shown in Table 1, risk estimates for all commodities are less than 100% of the aPAD for all subpopulations when considering the 99.9th percentile of exposure. The highest exposed

### *Dietary Risk from Food...*

subpopulation (children 1-6 years) is at 75% of the aPAD, and the general population is at 46% of the aPAD.

- EPA calculated the aPAD and dietary risk levels for carbaryl using the following data:
  - For the acute dietary assessment, the acute No Observed Adverse Effect Level (NOAEL) is 1 mg/kg/day from a developmental neurotoxicity study in rats. Increased incidence of neurological (functional observational battery) changes were observed on the first day of dosing in maternal animals at a Lowest Observed Adverse Effect Level (LOAEL) of 10 mg/kg/day.
  - The uncertainty factor (UF) is 100 for acute dietary risk, based on a 10x for standard uncertainties in applying animal studies to humans (interspecies extrapolation) and a 10x for varying effects among individuals (intraspecies variability).
  - The acute reference dose (acute RfD) is 0.01 mg/kg/day, calculated by dividing the NOAEL (1 mg/kg/day) by the UF (100).
  - The 10x Food Quality Protection Act Safety Factor (FQPA SF) was removed (i.e., is 1x) for all population subgroups. The Agency determined that this safety factor is adequate to protect infants and children because there are no residual uncertainties in the exposure databases, the toxicology database is complete, and the endpoint and NOAELs/LOAEL for risk assessment were well defined. In the toxicology database, no quantitative or qualitative evidence of increased susceptibility in rat or rabbit fetuses following *in utero* exposure in the standard developmental studies was observed. There was a low level of concern for evidence of susceptibility seen in the developmental neurotoxicity study, and there was evidence of increased susceptibility in offspring in the 2-generation reproduction study. However, the Agency believes that the acute and chronic RfDs would be protective of these effects so the FQPA SF was reduced to 1x.
  - The aPAD is 0.01 mg/kg/day, calculated by dividing the acute RfD (0.01 mg/kg/day) by the FQPA SF. Since the FQPA SF is 1x, the aPAD and the acute RfD are identical.
  - The acute dietary exposure analysis is based on the Dietary Exposure Evaluation Model (DEEM™), that uses exposure and consumption data to calculate risk as a percentage of the PAD. The DEEM™ analysis evaluated individual food consumption as reported by respondents in the USDA 1989-1992 Continuing Surveys for Food Intake by Individual (CSFII). For acute dietary risk assessments, the entire distribution of consumption events for individuals is multiplied by a randomly selected distribution of residues (probabilistic analysis, referred to as "Monte Carlo" ) to obtain a distribution of exposures.
  - The CSFII also has data for the years 1994 through 1998. Although these data are not yet routinely used in individual chemical assessments, EPA has developed risk estimates for

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carbaryl using these data. The risk estimates are, in general, slightly higher than those using the 1989-1992 data, but still resulted in exposures less than 100% of the aPAD.

- The anticipated pesticide residues on food are extensively refined for the acute dietary assessment and were derived from: (1) the Carbamate Market Basket Survey (CMBS), which was translated to similar commodities when feasible; (2) monitoring data from USDA's Pesticide Data Program (PDP); (3) FDA's Surveillance Monitoring Program; (4) the percentage of the crop treated (estimated maximum percentage); and (5) data from crop field trials where there were insufficient PDP or FDA monitoring data. Field trial data were used for the following commodities: garden beets, turnips, mustards, dried beans, almonds, pecans, walnuts, field corn grain, rice, flax seed, okra, olive, peanuts, pistachio, and sunflower.
- The Carbamate Market Basket Survey (CMBS) is an industry-sponsored, year long, national survey of carbamate residues on selected food commodities purchased at grocery stores. The CMBS collected up to 400 single-serve samples for 8 different crops (apple, banana, broccoli, grape, lettuce, orange, peach and tomato). Residue data from a market basket survey are generally considered to provide a close approximation to residues potentially found at the "dinner plate." Survey data are generally considered the most appropriate data source for use in pesticide risk and exposure assessment.

Information from the CMBS is being used in carbamate dietary risk assessments in conjunction with all other available field trial and monitoring data. It is acknowledged that the sample preparation protocol used by the CMBS introduces a degree of uncertainty into the reported survey results. The protocol (hand-rubbing certain commodities during the rinsing process) created a potential for residue loss prior to analysis; however, the degree to which this step had an effect on residue levels cannot be quantified. The Agency believes these survey data are useful to the carbaryl dietary risk assessment, as they tend to support PDP monitoring data findings of detectable residues on commodities important to the diets of infants and children.

EPA also conducted a separate assessment using solely the PDP/FDA monitoring data and field trial data for a better understanding of the overall risks. Use of this data set provides higher risk estimates than those based on inclusion of the CMBS carbaryl data. For example, using only PDP/FDA and field trial data, exposure for all infants (less than 1 year old) is 133% of the aPAD, and exposure for children 1 through 6 is 110% of the aPAD.

## **Chronic Dietary (Food) Risk**

Chronic (noncancer) dietary risk from food is calculated by using the average consumption value for foods and average residue values on those foods over a 70-year lifetime. As previously shown in Table 1, dietary exposure for all populations is less than 1% of the cPAD, and therefore not of concern to the Agency.

- EPA calculated the cPAD and dietary risk levels for carbaryl using the following data:
  - EPA used the Lowest Observed Adverse Effect Level (LOAEL) of 3.1 mg/kg/day for the chronic dietary assessment based on a 1-year chronic toxicity feeding study in dogs. Decreases in plasma and brain cholinesterase were observed in females at this dose. Because the LOAEL dose was the lowest dose tested, a NOAEL was not established.
  - The uncertainty factor (UF) is 300, based on a 10x for standard uncertainties in applying animal studies to humans (interspecies extrapolation) and a 10x for varying effects among individuals (intraspecies variability), as well as a 3x for the added uncertainty of using a LOAEL instead of a NOAEL.
  - The chronic reference dose (chronic RfD) is 0.01 mg/kg/day, calculated by dividing the LOAEL (3.1 mg/kg/day) by the UF (300).
  - The 10x Food Quality Protection Act safety factor (FQPA SF) was removed (i.e., is 1x) for all population subgroups, as discussed in the acute dietary section. The Agency determined that this safety factor was adequate to protect infants and children because there are no residual uncertainties in the exposure databases, the toxicology database is complete, and the endpoint and NOAELs/LOAEL for risk assessment were well defined.
  - The cPAD is 0.01 mg/kg/day, calculated by dividing the chronic RfD (0.01 mg/kg/day) by the FQPA SF. Because the FQPA SF is 1x, the cPAD and the chronic RfD are identical.
  - The chronic dietary exposure analysis is based on the Dietary Exposure Evaluation Model (DEEM™), which incorporates exposure and consumption data to calculate risk as a percentage of the cPAD. The DEEM™ analysis evaluated individual food consumption as reported by respondents in the USDA 1989-1992 Continuing Surveys for Food Intake by Individual (CSFII). For chronic dietary risk assessments, a 3-day average consumption for each subpopulation is combined with average residues in commodities to determine average exposures. Using the 1994-1998 CSFII data does not alter the results.
  - The anticipated pesticide residues on food are extensively refined for the chronic dietary assessment for food and derived from: (1) monitoring data from USDA's Pesticide Data

### *Dietary Risk from Food...*

Program (PDP); (2) FDA's Surveillance Monitoring Program; (3) the percentage of the crop treated (weighted average); and (4) data from crop field trials where there were insufficient PDP or FDA monitoring data. Field trial data were used for the following commodities: garden beets, turnips, mustards, dried beans, almonds, pecans, walnuts, field corn grain, rice, flax seed, okra, olive, peanuts, pistachio, and sunflower. CMBS data are not used for chronic dietary assessment because they reflect single-serving residue values.

### **Cancer Dietary (Food) Risk**

Cancer dietary risk from food is also calculated by using the average consumption values for food and average residue values for those foods over a 70-year lifetime. The chronic exposure value is multiplied by a linear low-dose response factor ( $Q_1^*$ ), based on animal studies, to determine the lifetime cancer risk estimate. For cancer dietary exposure, risk estimates less than  $1 \times 10^{-6}$  (1 in 1 million) are not of concern to the Agency.

- Carbaryl is classified as "likely to be carcinogenic to humans," based on vascular tumors in mice (males). The unit risk, or  $Q_1^*$  value, is  $8.75 \times 10^{-4} \text{ (mg/kg/day)}^{-1}$ .
- The maximum estimated lifetime cancer dietary (food) risk of  $2.8 \times 10^{-8}$  for the general US population is not of concern. Use of the 1994-1998 CSFII has no impact on the overall results.

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### ***Dietary Risk from Drinking Water***

Drinking water exposure to pesticides can occur through surface and ground water contamination. EPA considers both acute (one day) and chronic (lifetime) drinking water risks and uses either modeling or actual monitoring data, if available and of sufficient quality, to estimate those risks. To determine the allowable carbaryl exposure from drinking water, or the Drinking Water Level of Comparison (DWLOC), EPA first looks at how much of the overall allowable dietary risk is contributed by food. For carbaryl, EPA calculated food risk including the results of the Carbamate Market Basket Survey. The DWLOC is the amount of allowable risk left for exposure through drinking water. The DWLOC is then compared to a drinking water estimated environmental concentration (drinking water EEC). If the DWLOC is higher than the drinking water EEC, then the risk is not of concern to the Agency. Below is a discussion of the drinking water EECs for carbaryl, followed by a comparison of the DWLOCs to the drinking water EECs to assess risks.

## *Dietary Risk from Drinking Water...*

### Estimated Environmental Concentrations for Carbaryl

- Carbaryl is fairly mobile, but is not likely to persist or accumulate in the environment. As such, it is difficult for monitoring studies to detect peak concentrations that can occur. EPA determined that currently available monitoring studies for carbaryl are limited in this regard, and did not use them to define peak values for carbaryl. Instead, EPA used computer modeling to estimate drinking water EECs from ground and surface water that could be expected from normal agricultural use. Modeling is designed to provide a high-end estimate of exposure.
- A primary degradate of carbaryl is 1-naphthol. The Agency is not, however, concerned about levels of 1-naphthol in drinking water for this assessment. Due to the limited persistence of 1-naphthol, it is not expected to be found in significant concentrations resulting from carbaryl applications, and even if found, it is not a cholinesterase inhibitor nor is it expected to be carcinogenic.
- Drinking water EECs for surface water were estimated using computer modeling with PRZM/EXAMS software, scenarios using an Index Reservoir, and a Percent Crop Area factor. Drinking water EECs from modeling vary depending on different scenarios for geographic location, crop, and pesticide application rates.
- Drinking water EECs for surface water were estimated using five crop scenarios: (1) Ohio Sweet Corn, (2) Ohio Field Corn, (3) Oregon Apples, (4) Minnesota Sugar Beets, and (5) Florida Citrus. These scenarios were selected to represent the range of crops and use rates likely to result in higher environmental concentrations. These scenarios were also modeled at different application rates: label maximum application rate, average application rate (based on EPA's data review), and reported maximum application rate (from DOANE survey data).
- Drinking water EECs for groundwater were estimated using the SCI-GROW computer model based on the upper-end agricultural application rate for carbaryl use on citrus. SCI-GROW provides a screening value to use in determining exposure and the potential risk to human health.

### Modeled Risk Estimates

The DWLOCs and drinking water EECs for carbaryl are presented in Table 2. Drinking water EECs that are higher than DWLOCs are bolded.



*Dietary Risk from Drinking Water...*

**Table 2.** DWLOCs for Combined Food and Drinking Water Exposure and Drinking Water EECs for Carbaryl at the Maximum Label Application Rate

Population Subgroup	Acute DWLOCs and Drinking Water EECs (ppb) for Surface Water						Drinking Water EEC (ppb) for Ground Water
	DWLOC	Drinking water EECs (Modeling) at Maximum Label Application Rates					
		Florida Citrus	Oregon Apples	Ohio Sweet Corn	Ohio Field Corn	Sugar Beets	
U.S. Population	188	494	144	37	30	19	0.8
All Infants (<1yr)	27	494	144	37	30	19	
Children 1-6	27	494	144	37	30	19	
Children 7-12	38	494	144	37	30	19	
	Chronic (noncancer) DWLOCs and Drinking Water EECs (ppb) for Surface Water						
U.S. Population	349	28	9	3	2	2	
All Infants (<1yr)	100	28	9	3	2	2	
Children 1-6	99	28	9	3	2	2	
Children 7-12	100	28	9	3	2	2	
	Cancer DWLOCs and Drinking Water EECs (ppb) for Surface Water						
U.S. Population	39	28	9	3	2	2	

*Acute Drinking Water Risk Estimates for Surface Water*

- For surface water, using the label maximum application rates for carbaryl in the model, acute drinking water EECs exceed the DWLOCs for infants (less than 1 year) and children (1 to 6 years) for combined food and drinking water exposure in four of the five scenarios, with modeled drinking water EECs for surface water ranging from 30 ppb for Ohio Field Corn to approximately 500 ppb for Florida Citrus. Only the EECs for Minnesota Sugar Beets (19 ppb) were less than the DWLOCs for all population subgroups.
- The Agency has also assessed drinking water concentrations based on average application rates (based on usage data) and reported maximum application rates (based on DOANE survey data). These rates are generally lower than the maximum label application rate, resulting in less exposure and fewer risks of concern.

### *Dietary Risk from Drinking Water...*

- The highest carbaryl drinking water EEC for surface water (494 ppb), which is from the maximum label application rate on Florida citrus, is presented with the notation that the majority of drinking water in Florida (greater than 90%) is derived from ground water. Therefore, potential high surface water concentrations would not necessarily indicate widespread, high exposure. The aggregate risk assessment therefore uses for comparison the next highest drinking water EEC, Oregon apples at the label maximum application rate (144 ppb).

#### *Chronic Drinking Water Risk Estimates Surface Water*

- Chronic (noncancer) and cancer drinking water risk estimates from surface water are significantly less than the DWLOCs and are not of concern for combined food and drinking water exposures. Chronic (noncancer) drinking water EECs for surface water range from 0.7 to 28 ppb for both average and maximum rates, significantly less than the chronic DWLOCs for carbaryl. Cancer drinking water EECs are also significantly less than the cancer DWLOCs.

#### *Drinking Water Risk Estimates for Groundwater*

- The modeled drinking water EEC for groundwater is 0.8 ppb, and is significantly less than the acute and chronic (cancer and noncancer) DWLOCs for combined food and drinking water exposure.

#### Monitoring Data

- EPA lacks a targeted drinking water monitoring study for carbaryl to compare with the screening-level modeling results presented above. Carbaryl is the second most widely detected insecticide in surface water, based on the USGS NAWQA database, with a significant portion apparently transported to streams. Out of 5220 surface water samples analyzed, about 21% (1082) had detections greater than the minimum detection limit. The maximum observed concentration for carbaryl in surface water from the non-targeted USGS NAWQA study is 5.5 ppb. The maximum observed concentration from a California state surface water database is 8.4 ppb, cited in EPA's environmental risk assessment for carbaryl. Both differ significantly from the 494 ppb peak value from computer modeling. The registrant submitted interim results from an ongoing targeted monitoring study of carbaryl surface water concentrations. However, the interim data are not sufficient to serve as the basis for the drinking water EECs in this risk assessment.

Another finding in the NAWQA data is that streams draining urban areas showed more frequent detections and higher concentrations than streams draining agricultural or mixed land use areas. EPA has limited tools for assessing the effects of pesticide use in urban and suburban settings on surface water and groundwater quality, and may need additional data to provide estimates of the distribution of possible exposures.

## ***Residential Risks***

### Use Summary

- Residents can receive nondietary exposures to carbaryl by mixing, loading, or applying pesticides (**residential handler exposure**), or by re-entering an area after treatment (**residential post-application exposure**) by homeowners or commercial pest control applicators. Residential exposures are broadly defined to include all non-dietary, non-occupational exposures, including recreational activities like golfing, and any other exposures than can occur in the general population.
- Carbaryl has a wide variety of residential uses, including lawns, gardens, ornamentals, and pets. Other than pet treatment, there are no registered indoor uses. Carbaryl is used on golf courses, and may be used in public areas, such as schools or parks. Although EPA is not aware of public health uses of carbaryl in state or local mosquito control programs, it is labeled as a mosquito adulticide, which EPA did consider in the risk assessment. There is also potential exposure from carbaryl used in Washington State to control burrowing shrimp in oyster beds. EPA also considered this special local need (FIFRA 24c) use on oyster beds in the risk assessment.
- Both homeowners (and professional applicators) can apply carbaryl by many methods, including trigger sprayers, hose-end sprayers, granular spreaders, ready-to-use dust packaging, low pressure handwand sprayers, backpack sprayers, and turfguns.
- Residential handlers may be exposed to carbaryl residues via the dermal (skin) and inhalation routes. Post-application exposures to carbaryl for adults are most likely through the skin, whereas children may also receive oral exposures from mouthing behaviors (i.e., hand-to-mouth, object-to-mouth, and soil ingestion).

### Noncancer Toxicity Summary

- To estimate noncancer residential risks, the Agency calculates the ratio of the NOAEL selected for risk assessment to the exposure. This margin of exposure ( $MOE = NOAEL / \text{exposure}$ ) is compared to a target MOE. The total target MOE is based on uncertainty factors (UFs) that are routinely applied to residential risk assessments: 10x to account for interspecies extrapolation and 10x to account for intraspecies variations, plus any additional safety factor retained due to concerns unique to the protection of infants and children under FQPA. An MOE less than 100 is generally of concern to the Agency.
- For carbaryl, the 10x FQPA SF has been removed (i.e., is 1x), for reasons explained above in the acute dietary section. Therefore, the target MOE for short- and intermediate-term exposures is 100. For long-term exposures, the target MOE is 300, because the lowest dose tested in the long-term study was the LOAEL, and a 3x uncertainty factor was added to account for uncertainties from using a LOAEL in place of a NOAEL. The only residential long-term assessment for residential use is the postapplication exposure of toddlers to pet collars.

### *Residential Risk...*

- The NOAELs and LOAELs used in the residential risk assessment are summarized below:
  - Short- and intermediate-term dermal risk assessments for carbaryl are based on a NOAEL of 20 mg/kg/day from a 28-day dermal toxicity study in rats using technical grade carbaryl. Decreases in red blood cell cholinesterase in males and females, and decreases in brain cholinesterase in males, were observed at the systemic LOAEL of 50 mg/kg/day.
  - Short-term inhalation and incidental, nondietary ingestion risk assessments for carbaryl are based on a NOAEL of 1 mg/kg/day from a developmental neurotoxicity study in rats. Increased incidence of neurological (functional observational battery) changes and cholinesterase inhibition (red blood cell, plasma, whole blood, and brain) were observed at the LOAEL of 10 mg/kg/day. Since an oral study was used for these risk assessments, a 100% absorption factor was applied to extrapolate for the inhalation assessments.
  - Intermediate-term inhalation risk assessments for carbaryl are based on a NOAEL of 1 mg/kg/day from a subchronic neurotoxicity study in rats. Increased incidence of neurological function changes and cholinesterase inhibition (red blood cell, plasma, whole blood, and brain) were observed at the LOAEL of 10 mg/kg/day. Since an oral study was used for these risk assessments, a 100% absorption factor was applied to extrapolate for the inhalation assessments.
  - The long-term (greater than 6 month) exposure assessment for pet collars is based on a 3.1 mg/kg/day LOAEL from a 1-year chronic toxicity feeding study in dogs. Decreases in plasma and brain cholinesterase in females were observed at this dose. Because the LOAEL dose was the lowest dose tested, a NOAEL was not determined. Therefore, the target MOE is 300 (which includes a 3x uncertainty factor for use of a LOAEL in place of a NOAEL). Since an oral study was used for these risk assessments, a 12.7% absorption factor was used to extrapolate for the dermal assessments.

### **Noncancer Risks for Residential Handlers**

- EPA assessed only short-term (1 to 30 day) exposures for residential handlers. Intermediate-term exposures (30 days to several months) are unlikely because of the sporadic nature of applications by homeowners.
- Maximum label application rates and use information specific to residential products served as the basis for the risk calculations. If additional information was available, such as average or typical rates, EPA used these values to allow for a more informed risk management decision. In most cases, these rates differed from maximum application rates by about a factor of two.
- Exposure values in this assessment were based on three carbaryl-specific residential handler studies. EPA also used two other sources of surrogate information: a study from the Outdoor

### *Residential Risk...*

Residential Exposure Task Force, of which Aventis is a member, and the Pesticide Handlers Exposure Database (PHED).

- EPA assessed 17 major residential handler exposure scenarios, based on anticipated use patterns and current labeling for carbaryl, as well as the types of equipment and techniques used by homeowners to apply carbaryl. Most of the 17 scenarios include more than one site/area/rate combination. Table 3 presents the scenarios EPA considered and their associated risk estimates. Of these scenarios, 8 are of concern (MOEs are less 100), and these scenarios and MOEs are shown in bold. In all cases, dermal exposure is the primary contributor to risk.

**Table 3.** Carbaryl Noncancer MOEs for Combined Short-term Residential Handler Dermal and Inhalation Exposures

#	Scenario Descriptor	Use Site	Amount of Carbaryl Used (lb ai/event)	Combined Dermal and Inhalation MOEs
1	Garden: Ready-to-Use Trigger Sprayer	Vegetables/Ornamentals	0.012 to 0.00075	2100 to 33730
2	<b>Garden/Ornamental Dust</b>	Vegetables/Ornamentals	0.4 to 0.079	<b>21 to 85</b>
			0.079*	107
3	<b>Garden: Hose-End Sprayer</b>	General Use (2% soln)	2	<b>21</b>
		Fire Ants	0.75	<b>55</b>
		Other Uses: Perimeter Nuisance Pests, Vegetables, Vegetables/Ornamentals,	0.26 to 0.012	158 to 3427
4	Garden: Low Pressure Handwand	General Use (2% soln), Perimeter Nuisance Pests, Vegetables, Ornamentals, Fire Ant	0.19 to 0.012	193 to 3056
5	Trees/Ornamentals: Low Pressure Handwand	Ornamentals, Pome Fruits, Nuts/Stone Fruits, Citrus	0.176 to 0.023	142 to 1084
6	<b>Trees/Ornamentals: Hose End Sprayer</b>	Ornamentals, Pome Fruits, Nuts/Stone Fruits, Citrus	0.5*	<b>72</b>
			0.176 to 0.023	204 to 1559
7	Garden: Backpack Sprayer	General Use (2% soln), Perimeter Nuisance Pests, Vegetables, Vegetables/Ornamentals, Fire Ants	0.19 to 0.012	1293 to 20468
8	<b>Lawn Care: Hose End Sprayer</b>	Lawn (broadcast)	5	<b>25</b>
		Lawn (spot)	0.25	495
9	<b>Dogs: Dusting</b>	Dog	0.0026	142
			0.1	<b>4</b>
			0.05	<b>7</b>
10	Dogs: Liquid Application	Dog	0.001	14000000*
11	<b>Granular &amp; Baits Lawn Care: Belly Grinder</b>	Lawn (spot)	0.21	<b>60</b>
			0.1	126

*Residential Risk...*

#	Scenario Descriptor	Use Site	Amount of Carbaryl Used (lb ai/event)	Combined Dermal and Inhalation MOEs
12	Granular & Baits Lawn Care: Push-Type Spreader	Lawn (broadcast)	4.2 to 2	477 to 1003
13	<b>Granulars &amp; Baits By Hand</b>	Ornamentals and Gardens	0.21	<b>15</b>
14	<b>Aerosol</b>	Various	0.08	<b>65</b>
15	Collars: Pet	Dog	0.013	10800000*
16	Sprinkler Can (Source: Scenario 6)	Ornamentals (2% solution)	0.1	359
17	Ornamental Paint On	Ornamentals (2% solution)	0.02	297
*Average use rate based on exposure study data.				
** These scenarios reflect dermal MOEs only, and are based on EPA's SOPs for Residential Exposure Assessment as opposed to monitoring data.				

### Noncancer Risks for Residential Postapplication Exposures

Several carbaryl-specific studies were used in developing this assessment, including a turf transferable residue study conducted in California, Georgia, and Pennsylvania at approximately 8 lb ai/acre. This study was conducted using the standard protocol from the Outdoor Residential Exposure Task Force. The Agricultural Reentry Task Force conducted several dislodgeable foliar residue studies with carbaryl. The olive pruning and cabbage weeding studies were used in the home garden risk assessments.

EPA assessed the risks from postapplication exposure to carbaryl residues for the following populations: Adult Residential (homeowner); Youth-aged children (10-12 years old); and Toddlers (3-year olds). EPA considered short- (1 to 30 days) and intermediate-term (30 days to several months) exposures. The only long-term exposure considered (greater than 6 months) is for pet collar uses.

#### *Adult Residential Postapplication*

- EPA assessed the following 5 scenarios for adult residential postapplication exposures: residential turf for lawncare and after mosquito control; recreational swimming and beach activity (following oyster bed treatments); golfing; home garden exposure to deciduous trees; and home garden exposure to fruiting vegetables. Within each scenario, ranges of exposure were evaluated for different application rates, duration of exposure, and postapplication activities (e.g., weeding, harvesting). Of the 5 scenarios, only 1 is of concern: short-term risks from lawncare (i.e., heavy yardwork).
- On the day of application, the short-term MOE for lawncare is 43 at an application rate of 8 lb ai/acre. After about 5 days, residues dissipate below the level of concern. At a lower application rate of 4 lb ai/acre, the MOE on the day of application is 88, and it takes about 1 day for residues to dissipate below the level of concern. All the remaining MOEs are greater than 500, with most in the thousands to tens of thousands. Similarly, all intermediate-term exposures for residential turf are greater than 400.

## *Residential Risk...*

### *Youth-aged Children (10 to 12 year-olds)*

- Children of this age can help with garden maintenance, and therefore are considered for postapplication activities related to fruiting vegetables and fruit trees (such as weeding and harvesting). The MOEs for these activities, both short and intermediate-term, were all greater than 100 on the day of application, and therefore not of concern. The lowest MOEs are approximately 650 for high exposures from deciduous trees and 980 for high exposures from fruiting vegetables; the rest of the MOEs are significantly greater than 1000.

### *Toddlers (3 year-olds)*

- Toddlers were selected as a representative population for turf and companion animal risk assessments to provide the most conservative risk estimates. Exposures from turf were evaluated separately for lawncare uses and after mosquito control. Beach activity following oyster bed treatment was also evaluated. The assessment is based on combined risk estimates for several routes of exposure: dermal, hand-to-mouth, object-to-mouth, and soil ingestion.
- Pet treatments result in short-term risks of concern for toddlers, (MOE less than 100) even 30 days after application, regardless of whether the formulation used was a dust, liquid or collar. Hand-to-mouth and dermal exposures are approximately equal contributors to the overall estimates for each product type. Intermediate-term risk concerns for pet treatments are similar to the short-term risk concerns. One use, pet collars, is assessed as a long-term exposure, and is also of concern for toddlers (MOE=43). Pet collars are assumed to be worn by pets all of the time so long-term exposures to toddlers may occur.
- Treated turf exposures (from products labeled for direct application to turf) also result in short-term risks of concern for toddlers. The MOEs are less than 100 on the day of application for both rates considered, 4 lb ai/acre (MOE=11) and 8 lb ai/acre (MOE=5). These applications required 14 days and 18 days, respectively, to reach the target MOE. Intermediate-term risks to toddlers improve, based on 30-day average exposures and the dissipation rate for carbaryl, but the MOEs (91 and 45, respectively) are still of concern. Dermal and hand-to-mouth exposures are the key contributors, while soil ingestion and object-to-mouth exposures were a minor contributors to the total risk estimates.
- Turf exposures following application of carbaryl as a mosquito adulticide are not of concern, regardless of how applications are made (i.e., by ground or air). Both short-term (on the day of application) and intermediate-term MOEs are equal to or greater than the target MOE of 100. The lowest MOEs are approximately 450 for aerial application and 850 for ground application, with the remaining MOEs ranging from the thousands to more than one hundred thousand.
- Postapplication risks for toddlers playing on the beach after oyster bed treatment with carbaryl are not of concern to the Agency. Short-term MOEs are greater than 100, even if the highest monitored sediment concentration value from any study available to the Agency was used as the basis for the calculations. The intermediate-term results were similar. The lowest MOE is in the tens of thousands.

### **Cancer Risks for Residential Handlers**

- Carbaryl is classified as “likely to be carcinogenic to humans,” based on increased incidence of vascular tumors in mice. Cancer risks are calculated by multiplying the Lifetime Average Daily Dose (LADD), which represents dermal and inhalation exposure amortized over a lifetime, by the  $Q_1^*$  or unit risk, which is a quantitative dose response factor. The  $Q_1^*$  for carbaryl is  $8.75 \times 10^{-4} \text{ (mg/kg/day)}^{-1}$ .
- For the 17 handler scenarios considered in EPA’s residential handler assessment, cancer risks are not of concern to the Agency; the risks are equal to or less than  $1 \times 10^{-6}$  (most are in the  $10^{-8}$  or  $10^{-10}$  range) when evaluating a single application per year.
- EPA also calculated, for each scenario, the maximum number of days of exposure per year that could occur with estimated risks still at or below the  $1 \times 10^{-6}$  risk level (i.e., not of concern). There are 5 scenarios where the maximum number of exposures at or below the  $1 \times 10^{-6}$  risk level is 5 days or fewer.

### **Cancer Risks for Residential Postapplication Exposures**

- Postapplication cancer risks were calculated only for adults and considered the same scenarios used for assessing noncancer risks.
- For all scenarios on turf, cancer risks are not of concern to the Agency; risks were in the  $10^{-8}$  range or less on the day of application when evaluating a single reentry event per year during lawncare activities. Risks from home gardening, golfing, mosquito control, or oyster bed treatment, are also not of concern; they were in the  $10^{-9}$  to  $10^{-12}$  range when evaluating a single reentry event per year on the day of application.
- The Agency calculated, for each scenario, the maximum number of days of exposure per year which could occur and risks would be at or below  $1 \times 10^{-6}$  (i.e., not of concern). Values range from 20 to over 365 days per year, while most exceed 365 days per year even on the day of application.

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### ***Aggregating Risks from Food, Drinking Water and Residential Uses***

Aggregate risks for dietary exposures from food and drinking water were described earlier. This section describes the aggregate (combined) risk from food, drinking water *and* residential exposures.

EPA generally does not calculate aggregate risks when dietary or residential risks are already of concern. In this case, however, EPA did generate an aggregate risk assessment to help inform risk management decisions.



## Aggregating Risks...

The purpose of the aggregate assessment is to identify risks that become a concern when combined with others. Therefore, residential risks already known to be of concern alone are not part of this aggregate assessment for carbaryl. Instead, EPA selected representative scenarios where residential risks alone are not already of concern.

These scenarios include both postapplication and handler exposures. Postapplication exposures include: mosquito control; swimming/beach activity (after oyster bed treatments); golfing; and garden harvest. The handler scenarios are mostly at the average application rate based on study data. The maximum application rates for these scenarios were not used because they are already of concern by themselves. The handler scenarios selected include: application of dusts to gardens and pets; hose end sprayer; liquid spray spot lawn treatments; and broadcast application of granulars to lawns.

- After aggregating the dietary (food) and residential exposures *not already of concern*, EPA determined, for each assessed activity, the DWLOC (i.e., the allowable room left for drinking water exposure).
- EPA compared the calculated DWLOCs to the chronic drinking water EECs from both surface water and ground water. For drinking water EECs from surface water, results from carbaryl use on Florida citrus and Oregon apples were used for comparison with the DWLOC because they are the two highest drinking water EECs for carbaryl.

### Short-term Aggregate Risks

- For those scenarios that are not residential risk concerns alone, all DWLOCs are greater than the chronic drinking water EECs (i.e., are not of concern), except for the DWLOC (19 ppb) for adults using garden dust use at the average application rate, which is less than the EEC (28 ppb) from carbaryl use on Florida citrus use. The DWLOC, however, is greater than the chronic drinking water EECs for ground water (EEC of 0.8 ppb), or for surface water from the Oregon apple use (9 ppb).

### Intermediate-term Aggregate Risks

- EPA did not calculate separate intermediate-term aggregate risk estimates. The results would essentially be the same as the short-term aggregate risk estimates because the hazard inputs are numerically identical. Intermediate-term postapplication exposures, though, would be lower, because they represent a 30-day average rather than the single-day higher exposure estimate used for short-term exposures.

### Cancer Aggregate Risks

- Aggregate cancer risks are not of concern for any subpopulation regardless of the source of drinking water, even considering the high-end drinking water EECs for Florida citrus. For the cancer risks, EPA used the same adult scenarios as the short-term risk assessment.

## ***Occupational Risk***

- The occupational risk assessment addresses on the job risks to pesticide workers who may be exposed to carbaryl when mixing, loading, or applying a pesticide (i.e., handlers), and when entering treated sites for routine tasks (postapplication).
- Occupational noncancer risk is being measured using the same MOE approach, and the same NOAELs and LOAELs, as are used in the residential assessment (see the Toxicology Summary heading in the residential section). However, the occupational assessment does not consider a FQPA SF for sensitive populations (infants or children).

### **Noncancer Risks for Occupational Handlers**

#### Use Scenarios

- The Agency identified 28 major occupational exposure scenarios based on the equipment and techniques that could be used for carbaryl applications, and within these scenarios there are 128 different crop/rate/acres combinations. These scenarios represent short-term (1 to 30 days) and intermediate-term (30 days to several months) exposures. A few scenarios were also assessed for long-term exposures (more than 180 days), mostly in the greenhouse and floriculture industry where long-term exposures could be expected. All scenarios present the combined risk from dermal and inhalation exposures.
- Occupational handler risk assessments were conducted considering eight levels of personal protection based on different combinations of the following:
  - (1) baseline protection (typical work clothing or a long-sleeved shirt and long pants, no respiratory protection and no chemical-resistant gloves);
  - (2) minimum personal protective equipment (baseline scenario with the use of chemical-resistant gloves and a dust/mist respirator with a protection factor of 5);
  - (3) maximum personal protective equipment (baseline scenario with the use of an additional layer of clothing (e.g., a pair of coveralls), chemical-resistant gloves, and an air purifying respirator with a protection factor of 10); and
  - (4) engineering controls (e.g., closed tractor cab or closed loading system for granulars or liquids).

Current labels mostly specify single-layer clothing, chemical-resistant gloves, and no respirator.

- The maximum application rates allowed by labels were used in the risk assessments. If additional information was available, such as average or typical rates, these values were used as well for a better understanding of the overall risks.
- The unit exposure values (mg ai exposure/lb ai handled) used in this assessment were predominantly based on the Pesticide Handlers Exposure Database (PHED). In addition to PHED, five exposure studies were used by the Agency to estimate exposures for: (1) professional dog groomers; (2) granular products using a backpack application device (two studies); (3) a ready-to-use trigger sprayer; and (4) professional lawn care operators using granular and liquid products.

**Risk Summary**

*Short-term and Intermediate-term risks.* The risk assessment for short- and intermediate-term occupational exposures are similar because the toxicity endpoints (NOAELs) are numerically the same, and the target MOE of 100 is the same for both durations.

- Out of the total of 128 crop/rate/area combinations assessed, 110 crop/rate/area combinations resulted in MOEs that meet or exceed the target MOE of 100 at some level of personal protective equipment (PPE) or engineering controls, but usually at a higher level than that specified on the current label.
- The remaining crop/rate/acreage combinations resulted in MOEs that are less than the target MOE, even at the highest practical levels of PPE and engineering controls. Of these, 8 are aerial uses; 2 are wide area ground uses; 3 are granulars and baits applied by spoon, hand, or bellygrinder; 2 are for hand-held devices; and 1 is for an animal groomer using a liquid application. Also, 2 crop/rate/area combinations for poultry use were assessed; however, Aventis has since submitted a letter to EPA requesting voluntary cancellation of the poultry use.
- Table 4 below summarizes these remaining noncancer risks of concern for occupational handlers for short- and intermediate-term exposure durations that do not meet the target MOE, even after considering the highest level of PPE and engineering controls.

**Table 4.** Noncancer Risks of Concern for Occupational Handlers, Short- and Intermediate-Term Durations at Highest Level of PPE Practical

Scenario	Rate (lb ai/acre)  [unless noted]	Area Treated (acres/day)  [unless noted]	Risk Summary: Combined Dermal/ Inhalation MOEs
<b>Mixer/Loaders</b>			
1f Dry Flowable: Wide area aerial	2 (rangeland/forestry)	7500	<b>58</b>
3a Liquid: Aerial/Chemigation	1.5-2 (wheat, max corn) 5 (stone fruit)	1200 350	<b>57-76</b> <b>78</b>
3f Liquid: Wide area aerial	2 (Range/Forestry) 1 (Mosquito adulticide)	7500 7500	<b>9</b> <b>18</b>
3g Liquid: Wide area ground	1 (Mosquito adulticide)	3000	<b>45</b>
4a Wettable Powders: Aerial	1-2 (Wheat/corn) 5 (stone fruit)	1200 350	<b>40-80</b> <b>55</b>
4f Wettable Powders: Wide area aerial	2 (Range/Forestry)	7500	<b>6</b>

*Occupational Risk...*

Scenario	Rate (lb ai/acre)  [unless noted]	Area Treated (acres/day)  [unless noted]	Risk Summary: Combined Dermal/ Inhalation MOEs
<b>Applicators</b>			
5a Aerial: Agricultural uses, liquid sprays	2 (max corn)	1200	<b>85</b>
5b Aerial: Wide area uses, liquid sprays	2 (Range/Forestry) 1 (Mosquito adulticide- max rate)	7500 7500	<b>14</b> <b>27</b>
5c Aerial: Agricultural uses, granular applications	2 (corn) 2 (corn)	1200 350	<b>21</b> <b>72</b>
6b Airblast: Wide area uses, liquid sprays	1 (Mosquito adulticide - max rate)	3000	<b>22</b>
12 High pressure handwand	4 lb ai/100 gallons	1000 gallons	<b>66</b>
13 Animal groomer, liquid application	0.01 lb ai/dog	8 dogs	<b>10</b>
15 Granulars & baits applied by hand	9 (Ornamentals & gardens)	1	<b>4</b>
16 Granulars & baits applied by spoon	9 (Ornamentals & gardens)	1	<b>75</b>
<b>Mixer/Loader/Applicators</b>			
17 Low pressure, high volume turfgun (ORETF Data)	8 (LCO Use on turf)	5	<b>94</b>
20 Granular, bellygrinder	9 (Turf)	1	<b>27</b>

*Long-term risks.* Only a few occupational uses are expected to result in long-term exposures. Of 5 scenarios assessed, 3 meet or exceed the target MOE of 300 at some level of personal protection. The two scenarios that fail to meet or exceed the target MOE are scenario 15: granulars & baits applied by hand; and scenario 16: granulars and baits applied by spoon. Both were assessed at the maximum application rate of 9 lb ai/acre.

### Noncancer Risks for Occupational Postapplication Exposures

- For postapplication exposures, EPA calculates the minimum length of time required following an application before residues have dissipated to the level where the calculated MOE reaches the target MOE. EPA uses this information to determine restricted entry intervals (REIs), the time period after which workers are allowed to reenter a treated area. For carbaryl, the current label specifies a 12 hour REI.
- At the current REI, *short-term* MOEs are of concern (i.e., less than 100) for all but the lowest exposure scenarios in some crops. Table 6 summarizes the crop groups that result in risks of concern during *short-*, *intermediate-* and *long-term* postapplication exposures, and at different levels of exposure depending on the activity and contact with treated surfaces.

**Table 6.** Noncancer Risks of Concern for Occupational Postapplication Exposures

	<b>Low Exposure</b> (e.g., irrigation)	<b>Medium Exposure</b> (e.g., scouting)	<b>High Exposure</b> (e.g., hand harvesting)
<b>Short-term Exposure Duration</b> (1 to 30 days)	<u>Crop and # of days to reach target MOE</u>  Cut Flowers - 7 Evergreen Fruit Trees - 6 Brassica -6	<u>Crop and # of days to reach target MOE</u>  Cut Flowers - 9 Evergreen Fruit Trees - 17 Brassica - 9 Bunch/Bundle Group - 6 Low/Medium Field/Row Crops -3 Tall Field/Row Crops - 4 Sugarcane - 3 Root vegetables - 4 Curbit Vegetables - 4 Leafy Vegetables - 4 Stem/stalk Vegetables - 1 Vine/Trellis Group - 2	<u>Crop and # of days to reach target MOE</u>  Cut Flowers - 12 Evergreen Fruit Trees (No high exposure) Brassica - 11 Bunch/Bundle Group - 8 Low/Medium Field/Row Crops - 5 Tall Field/Row Crops - 11 Sugarcane - 7 Root vegetables - 7 Curbit Vegetables - 7 Leafy Vegetables - 7 Stem/stalk Vegetables - 5 Vine/Trellis Group - 11 Low Berry - 4 Fruiting Vegetable - 2 Deciduous Fruit Trees - 8 Nut Trees - 11 Turf/Sod - 14
<b>Intermediate-term Exposure Duration</b> (30 days to several months)	None	<u>Crop (calculated MOE)</u>  Evergreen Fruit Trees (MOE=59)	<u>Crop (calculated MOE)</u>  Cut Flowers (MOE=57) Evergreen Fruit Trees (No high exposure) Brassica (MOE=79) Tall Field/Row Crops (MOE=97) Turf/Sod (MOE=46) Vine/Trellis (MOE=79)
<b>Long-Term Exposure Duration</b> (greater than six months)	None	None	<u>Crop (calculated MOE)</u>  Cut flower industry (MOE=69).

### Cancer Risks for Occupational Handlers

Occupational cancer risks equal to or less than  $1 \times 10^{-6}$  (1 in 1 million) are not of concern to the Agency. The Agency also carefully examines uses with estimated risks in the  $10^{-6}$  to  $10^{-4}$  range to seek cost-effective ways of reducing risks. If carcinogenic risks are in this range for occupational handlers, increased levels of personal protective equipment (PPE) or engineering controls are added to the extent practical. The Agency considered two distinct populations for the carbaryl cancer risk assessment: private growers, at 10 applications per year, and commercial applicators at 30 applications per year.

*Private growers* (10 applications per year).

- Of the 128 scenario combinations considered for private growers, all scenarios have risks less than  $1 \times 10^{-6}$  at some level of PPE or engineering controls, except for 8 scenarios that have risks between  $1 \times 10^{-4}$  and  $10^{-6}$ . Of these 8 scenarios, only 1 needed a higher level of PPE than specified on the current label to have risks in this range.

*Commercial applicators* (30 applications per year)

- Of the 128 scenario combinations considered for commercial applicators, all have risks less than  $1 \times 10^{-6}$  at some level of PPE or engineering controls, except for 21 scenarios that have risks between  $1 \times 10^{-4}$  and  $10^{-6}$ . Of these 21 scenarios, only 1 needed a higher level of PPE than specified on the current label to have risks in this range.

### **Cancer Risks for Occupational Postapplication Exposures**

Based on a  $10^{-6}$  risk concern, the current REI appears adequate to address cancer risks for many crop/activity combinations. But for higher exposure situations, longer duration REIs are necessary for risks to cease to be of concern ( $\leq 10^{-6}$ ). In all cases, REIs based on cancer risks are less restrictive or similar (i.e., within a day or two of application for commercial farmworkers) than those based on the noncancer effects of carbaryl. In no cases do cancer risks indicate more restrictive REIs than for noncancer risks calculated for the corresponding exposure scenario.

*Private growers* (10 applications per year).

- All scenarios have risks in the  $10^{-6}$  range, except for one scenario (very high exposure for tall field/row crops), which was in the  $10^{-5}$  range. All risks in the  $10^{-6}$  range take up to approximately 5 days to fall below  $1 \times 10^{-6}$ . The risk in the  $10^{-5}$  range takes 23 days to fall below  $1 \times 10^{-6}$ .

*Commercial farmworkers* (30 applications per year).

- All scenarios had cancer risks in the  $10^{-6}$  range or less on the day of application at the current REI, except for two very high exposure activities (hand harvesting). All risks in the  $10^{-6}$  range take approximately 8 days to fall below  $1 \times 10^{-6}$ . The two very high exposure activities, for tall field/row crops and vine/trellis crop groups, have risks in the  $10^{-5}$  range on the day of application, and take 31 and 13 days, respectively, to fall below  $1 \times 10^{-6}$ .

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### ***Human and Domestic Animal Incidents***

- The Agency evaluated reports of human carbaryl poisonings and adverse reactions associated with its use from the following sources: OPP Incident Data System (IDS); Poison Control Centers' Toxic Exposure Surveillance System; California Department of Pesticide Regulation; the National Pesticide Telecommunications Network, now the National Pesticide Information Center (NPIC); open literature; and an unpublished study submitted by the registrant.

### *Human and Domestic Animal Incidents...*

- The data from IDS indicated that a majority of incidents associated with carbaryl exposure involved dermal reactions. A number of other cases involved asthmatics and people who experienced hives and other allergic type reactions. According to California data, about half of the cases involved skin and eye effects in handlers. About a quarter of the skin reactions were due to workers who were exposed to residues on crops. Reports from the literature are very limited but tend to support the finding that carbaryl has irritant properties.
  - The Poison Control Center cases involving nonoccupational adult exposure and exposures of older children showed an increased risk in five of the six measures used for comparing carbaryl incidents to all other pesticides. The carbaryl cases were almost twice as likely to require serious health care (hospitalization or treatment in a critical care unit) and were two and a half times more likely to experience major medical outcome (life-threatening effects or significant residual disability) than other pesticides. This pattern of increased risk was not seen among occupational reports or in young children, which may mean that careless handling by non-professionals is a particular hazard. In addition, five case report studies suggested that carbaryl may be a cause of chronic neurological or psychological problems.
  - The incident reports on domestic animals in IDS were evaluated. Based on limited data, there is some evidence that young kittens may be susceptible to adverse reactions to carbaryl.
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## ***Ecological Risk Assessment***

To estimate potential ecological risk, EPA integrates the results of exposure and ecotoxicity using the quotient method. Risk quotients (RQs) are calculated by dividing acute and chronic exposure estimates by ecotoxicity values for various wildlife species. RQs are then compared to levels of concern (LOCs); the higher the RQ, the greater the potential risk.

### ***Environmental Fate Information***

- Carbaryl dissipates in the environment by abiotic and microbially mediated degradation. The major degradation product is 1-naphthol, which is further degraded to CO<sub>2</sub>. Carbaryl is stable to hydrolysis in acidic conditions, but hydrolyzes in neutral (half-life=12 days) and alkaline environments (pH 9 half-life=3.2 hours). Under aerobic conditions the compound degrades rapidly by microbial metabolism, with half-lives of 4 to 5 days in soil and aquatic environments. In anaerobic environments metabolism is much slower, with half-lives on the order of 2 to 3 months. Carbaryl is moderately mobile in the environment. Open literature information suggests that its major degradate, 1-naphthol, is less persistent and less mobile than carbaryl.

## ***Nontarget Terrestrial Animal Risk***

### **Risks to Birds**

- The acute LOC for birds is 0.5 and the chronic LOC is 1.0.
- Nongranular uses of carbaryl are not expected to pose an acute risk to birds. Of the scenarios assessed, none exceed the LOC for birds in any weight class. Most nongranular uses of carbaryl do pose a chronic risk for birds.
- Granular uses of carbaryl pose an acute risk for 20 gram birds (highest RQ is 4.76). For 180 gram birds, uses that exceed the LOC are for trees/ornamentals, turf grass, and tick control. For 1000 gram birds, no granular uses exceed the LOC.

### **Risks to Mammals**

- The acute LOC for mammals is 0.5 and the chronic LOC is 1.0.
- Nongranular uses, at the maximum label application rate, pose acute risks above the LOC for mammals (highest RQ is 12). At rates below the maximum label rate (i.e., the maximum reported application rate and the average application rate), most uses exceed the LOC for 15 gram mammals feeding on short grass (highest RQ is 11). Practically all nongranular uses pose chronic risks that exceed the LOC (highest RQ is 48).
- Granular uses, at maximum label rates, pose acute risks that exceed the LOC for 15 gram and 35 gram mammals (highest RQs are 21.1 and 9.04 respectively), indicating that all granular carbaryl uses pose an acute risk to the smaller mammalian species. For 1000 gram mammals, no acute risks exceed the LOC.

## ***Nontarget Aquatic Animal Risk***

- The acute LOC for aquatic animals is 0.5 and the chronic LOC is 1.0.
- EPA examined risks to aquatic animals for estimated environment concentrations in surface water based on five crop scenarios for carbaryl: apples, field corn, sweet corn, citrus and sugar beets.
- Acute risks for freshwater fish exceed the LOC for use on citrus (highest RQ is 1.1). No scenario exceeded the chronic risk LOC.
- Acute risks for estuarine/marine fish do not exceed the LOC for any scenario. Data are not available to assess chronic risks.
- Acute risks for aquatic invertebrates, both freshwater and estuarine/marine, exceed the LOC for all scenarios. The acute RQs range from 0.8 to 161. Chronic risks for freshwater aquatic



### *Ecological Risk...*

invertebrates exceed the chronic LOC. The chronic RQs range from 1.7 to 91. No data are available to assess chronic risks to estuarine/marine invertebrates.

### ***Risks to Honeybees***

- Carbaryl is highly toxic to honey bees. It is one of the pesticides more often implicated in bee mortality incidents, ranking second and third respectively, in two separate bee kill surveys undertaken in 1997 by the Washington State Department of Agriculture and the American Beekeeping Federation.

### ***Nontarget Plant Risk***

- For terrestrial plants, the carbaryl label indicates that carbaryl may cause injury to tender foliage if applied when foliage is wet or during high humidity, and carbaryl may also harm Boston ivy, Virginia creeper, or maidenhair fern. A few reported incidents cite injury to vegetable crops (potatoes, tomatoes, cabbage and broccoli). However, not all guideline data are available to fully assess carbaryl risk to terrestrial plants.
- For aquatic plants, based on the single core green alga study available, the acute risk LOC is not exceeded for any of the five scenarios modeled, even at maximum label rates. However, not all guideline data are available to fully assess carbaryl risk to aquatic plants.

### ***Risks to Endangered Species***

- Acute endangered species LOCs for terrestrial animals (birds and mammals) is 0.1; for aquatic animals (freshwater or marine/estuarine fish and invertebrates) it is 0.05.
- Granular uses exceed the endangered species LOC for 20-gram birds, and they also exceed the LOC for 180-gram birds for most agricultural uses of carbaryl. For 1000-gram birds, RQs exceed the endangered species LOC for the trees and ornamentals, turf grass, and tick control uses. Nongranular uses of carbaryl do not exceed the avian endangered species LOC based on acute exposure.
- The endangered species LOC for mammals is met or exceeded for all uses at three application rates: maximum label, average (based on usage data), and maximum reported (based on DOANE survey).
- All carbaryl uses, even at less than maximum label rates, exceed the endangered species LOC for both freshwater and marine/estuarine aquatic invertebrates. At less than maximum label rates, the endangered species LOC is exceeded for freshwater fish only, based on the high-end citrus use scenario, and not exceeded for estuarine/marine fish for any of the five use scenarios modeled.

### ***Ecological Incident Data***

- Carbaryl does not rank high in the list of pesticides responsible for bird or mammal mortality, based on information available in the USEPA Ecological Incident Information System. Three bird kill incidents, classified as “probable,” involved blackbirds, ducks, starlings, and grackles in Virginia, New Jersey, and South Carolina. Only two incidents involved small mammals (grey and ground squirrels, mole, and rabbit) in South Carolina and Virginia. Numerous bee kill incidents have been recorded for carbaryl in several states including North Carolina, South Dakota and Washington. Additionally, several incidents on vegetable crops, including damage to potatoes, tomatoes, cabbage, and broccoli were classified as “probable.”
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### ***Summary of Pending Data***

Aventis has completed and is in the process of submitting (in August 2002) a residential postapplication biomonitoring study for lawn, and either a vegetable garden or ornamental flowers. Aventis will also submit (in October 2002) a biomonitoring study of field workers during harvesting and hand thinning operations in apples and cherries. Also, Aventis is a member of the Residential Exposure Joint Venture (REJV), which is a group of companies conducting a survey of homeowners to ascertain how consumer pesticide products are used (e.g., rate, frequency, pests, etc.). Aventis recently submitted an analysis of this data for carbaryl, which could be used to refine the exposure estimates in this assessment by refining the amounts of carbaryl used per homeowner application. In September 2002, Aventis will submit the final results of their surface water monitoring study for drinking water.